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Spectranetics
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510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92(c)

Prepared on March 11, 2014

510(k) Submitter / Holder: Spectranetics
9965 Federal Drive
Colorado Springs, CO 80921.3617
Establishment Registration No: 3007284006

Contact: Ms. Pharoah Garma
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Subject Device

Device Trade Name:	LexiPliant™ Dilator Sheath Set
Device Common Name:	Dilator Sheath
Device Class:	II
Classification Regulation:	21 CFR 870.1310
Regulation Description:	Vessel dilator for percutaneous catheterization
Product Code:	DRE
510(k) Type:	Traditional
Model Numbers:	Standard: 550-008, 550-010, 550-011, 550-013 Long: 555-508, 555-510, 555-511, 555-513

Predicate Device

The LEXiPliant Dilator Sheath Sets were compared to the following legally marketed predicate device:

510(k) Number:	K092378 (cleared on November 02, 2009)
Manufacturer:	Spectranetics Corp.
Trade Name:	VisiSheath™ Dilator Sheath
Device Common Name:	Dilator Sheath

Device Description

The LexiPliant Dilator Sheath Set family consists of an inner and outer polymer sheath that may be used individually or as a set in a telescoping fashion. The inner sheath terminates with beveled tips. The outer sheath terminates with one beveled tip and one blunt tip. The sheaths are designed to dilate tissue while facilitating the removal of cardiac leads, indwelling catheters and foreign objects. The device is introduced at a cardiac pacemaker or defibrillator pocket's implantation site and then advanced over the lead or object that is to be extracted. The rotation and progression of the inner and outer sheaths causes dilation of the tissue binding the lead or object within the vasculature. Upon dilation of the surrounding tissue, the lead or object can be removed by traction.

Intended and Indications for Use

The LexiPliant Dilator Sheath Set is intended for use in patients requiring the percutaneous dilatation of tissue to facilitate the removal of cardiac leads, indwelling catheters, and foreign objects.

The Spectranetics Corporation
9965 Federal Drive, Colorado Springs, CO 80921
Tel: 719-447-2000 • Fax: 719-447-2022

Technological Characteristics

The LexiPliant Dilator Sheath Set features similar design and functional characteristics as the predicate device (K092378 – VisiSheath Dilator Sheath Set). The results of design verification and validation testing demonstrate that the subject device is as safe and clinically effective as the predicate device.

Performance Data

The following testing was conducted to validate and verify that the subject device met all specifications and was substantially equivalent to the predicate device:

Design Verification and Validation Testing

- Dimensional Verification
- Tensile
- Cantilever Bend
- Dilatation
- Tip Compression
- Torque Tip
- Sheath Cycle
- Kink Fatigue
- Radiopacity

Sterilization

- Product adoption equivalency per AAMI TIR:28-2009

Biocompatibility

- Physiochemical
- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- C3a and SC5b-9 Complement Activation
- Indirect and direct Hemolysis
- *In Vivo* Thromobogenicity-Dog Model
- Material Mediated Pyrogenicity
- Genotoxicity – Ames Test

Preclinical and Clinical Data:

Preclinical and clinical data was not required to demonstrate substantial equivalence. The design characteristics of the subject device are similar to the predicate. The design verification and validation test results demonstrated that the subject device is as safe and clinically effective as the predicate device.

Substantial Equivalence

Based on the similarities in design between the subject and predicate device, and the performance data, the LexiPliant Dilator Sheath Set is substantially equivalent to the VisiSheath Dilator Sheath Set (K092378).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

Specranetics Corporation
% Pharoah Garma
Regulatory Affairs Manager
9965 Federal Drive
Colorado Springs, CO 80921-3617

Re: K133631
Trade/Device Name: LexiPliant™ Dilator Sheath Set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: February 25, 2014
Received: February 26, 2014

Dear Ms. Garma,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133617

Device Name
LexiPliant™ Dilator Sheath Set

Indications for Use *(Describe)*

The LexiPliant™ Dilator Sheath Set is intended for use in patients requiring the percutaneous dilatation of tissue to facilitate the removal of cardiac leads, indwelling catheters, and foreign objects.

Bram D. Zuckerman -S
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*